

REMARKS

Applicants thank the Examiner for indicating that claims 24-37, 46-56 and 59 are allowed. Claims 1-23, 38-45, 57-58, and 60-85 have been canceled without prejudice. Claims 86 and 88 have been amended to recite the phrase “at least 60.” Claim 87 has been amended to independent form and to recite the phrase “between 30 and 50.” No new matter has been added. After entry of this amendment, claims 24-37, 46-56, 59 and 86-88 will be pending.

I. Rejections under 35 U.S.C. §112, first paragraph – New Matter

Claims 86-88 have been amended to recite the phrases “at least 60” and “between 30 and 50.” Applicants believe that these amendments overcome this rejection of claims 86-88 under 35 U.S.C. §112, and respectfully request its reconsideration and withdrawal.

II. Rejections Under 35 U.S.C. § 112, first paragraph – Written Description

A. The Examiner rejected claims 1 and 36-135 under 35 U.S.C. § 112, first paragraph, as allegedly “containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.” *See* Paper No. 20041227, pages 2-3. Specifically, the Examiner contends that:

The claims encompass a genus of polynucleotide which can include many polynucleotides which differ in structure from SEQ ID NO:125 and 126. The genus is highly variant because it includes structural variants which differ in the activity of the polynucleotides.

See Paper No. 20041227, page 3, lines 1-4.

Applicants respectfully disagree and traverse this rejection.

The test for the written description requirement is whether one skilled in the art could reasonably conclude that the inventor has possession of the claimed invention in the specification as filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991); M.P.E.P. § 2163.02. The Federal Circuit recently re-emphasized the well-settled principle of law that “[t]he written description requirement does not require the applicant ‘to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [they]

invented what is claimed,” *Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989, 54 U.S.P.Q.2d 1227 (Fed. Cir. 2000). While the applicant must “blaze marks on trees,” rather than “simply [provide] the public with a forest of trees,” an Applicant is not required to explicitly describe each of the trees in the forest. *See Unocal*, 208 F.3d at 1000. *See also* M.P.E.P. § 2163.02 (“The subject matter of the claim need not be described literally (i.e., using the same terms or in haec verba) in order for the disclosure to satisfy the description requirement.”). The Court emphasized the importance of what the person of ordinary skill in the art would understand from reading the specification, rather than whether the specific embodiments had been explicitly described or exemplified. Indeed, as the court noted, “the issue is whether one of skill in the art could derive the claimed ranges from the patent’s disclosure.” *Unocal*, 208 F.3d at 1001 (emphasis added).

In an analysis of written description under 35 U.S.C. § 112, first paragraph, the Examiner bears the initial burden of presenting a *prima facie* case of unpatentability. This burden is only discharged if the Examiner can present evidence or reasons why one skilled in the art would not reasonably conclude that Applicants possessed the subject matter as of the priority date of the present application. *See In re Wertheim*, 541 F.2d 257, 262, 191 U.S.P.Q.2d 90, 96 (C.C.P.A. 1976); M.P.E.P. § 2163.04. In the instant case, Applicants respectfully submit that the Examiner has not met this burden.

Applicants respectfully disagree with the Examiner and submit that one skilled in the art would reasonably conclude that Applicants had possession of the polynucleotides encompassed by the rejected claims in the present application as filed. Applicants further submit that the Examiner has underestimated both the teaching of the present application and the level of skill in the art on the priority date of the present application.

Applicants respectfully submit that one skilled in the art, enlightened by teachings of the present application (particularly, for example, the sequences of SEQ ID NOS:125 and 126), could readily envision countless polypeptide sequences that comprise the specified polypeptides. For example, when provided with the sequences of SEQ ID NOS:125 and 126, the skilled artisan could clearly envision each of the polynucleotides that consist of at least 60 or between 30 and 50 consecutive nucleotides of SEQ ID NOS:125 and 126. Further, the instant claims do not require the claimed sequences to possess any particular activity or characteristic beyond the described sequence, and the

subject matter of what is claimed is fully supported by the specification. § 112 requires no more. See *Unocal*, 208 F.3d at 1000; M.P.E.P. § 2163.02.

Accordingly, from reading the specification, the skilled person would immediately recognize that, at the time the specification was filed, the Applicants had “invented what is claimed” (*Vas-Cath*, 935 F.2d at 1563); namely, a genus of polynucleotides consisting of at least 60 or between 30 and 50 consecutive nucleotides of SEQ ID NOS:125 and 126. Therefore, the specification contains an adequate written description of the claimed polypeptides.

For all of the above reasons, Applicants respectfully assert that the Examiner has failed to meet the required burden in presenting evidence or reasons why those skilled in the art would not recognize the claimed invention from the disclosure. Moreover, the specification conveys with reasonable clarity that Applicants were in possession of the claimed invention. Therefore, Applicants submit that the pending claims fully meet the written description requirements of 35 U.S.C. § 112, first paragraph, and respectfully request that the Examiner’s rejection of the claims under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

CONCLUSION

Applicants respectfully request that the remarks of the present response be entered and made of record in the present application. If any additional information is needed, Applicants respectfully request that the Examiner contact the undersigned to facilitate prosecution. The application is believed to be in condition for allowance and early notice to that effect is earnestly solicited. If a fee is required in connection with this paper, please charge Deposit Account No. 08-3425 for the appropriate amount.

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Respectfully submitted,


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